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10/681,013	10/07/2003	Lawrence M. Kauvar	388512010900	6212

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EXAMINER	
VENCI, DAVID J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	**Application No.** 10/681,013	**Applicant(s)** KAUVAR ET AL.
	Examiner David J. Venci	**Art Unit** 1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *July 28, 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 31, 2005, is entered.

Currently, claims 1-7 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 2, the recitation of the term “each” is indefinite. Whether “each” references an ordinal distinction or a distinction in class type is not clear.

In claim 1, line 2, the recitation of the pronoun "which" is indefinite. The object(s) referenced by "which" is/are not clear. Whether the pronoun "which" references "different label" and/or "particulate support" is not clear.

In claim 1, line 2, the recitation of the term "both" is indefinite. The objects required for membership to the class "both" are not clear. Whether "different labels" and/or "different label" and/or "particulate support" belong to the class "both" is not clear.

In claim 1, lines 2-5, the recitation of "both (a) to one or more..., and (b) to a second..." is indefinite. Whether a list is intended is not clear. The identity of list class and list objects are not clear.

In claim 1, line 3, the recitation of the pronoun "which" is indefinite. The object(s) referenced by "which" is/are not clear. Whether the pronoun "which" references "different label" and/or "particulate support" and/or "first signal-generating moieties" and/or "one or more first signal-generating moieties" is not clear.

In claim 1, line 3, the recitation of the term "together" is indefinite. The objects required for membership to the class "together" are not clear. Whether "different labels" and/or "different label" and/or "particulate support" and/or "first signal-generating moieties" and/or "one or more first signal-generating moieties" belong to the class "together" is not clear.

In claim 1, lines 4 and 9, the recitation of the term "characterizing signal" is indefinite. The object(s) or attribute(s) belonging to the class "characterizing" is/are not clear.

In claim 1, lines 4, 6-7 and 10-11, the recitations of "said label" or "said different labels" or "the label" or "said labels" are indefinite. Whether said recitations reference "a multiplicity of different labels" and/or "each different label" is not clear.

In claim 1, line 5, the recitation of the term "a second" is indefinite. Whether "a second" references an ordinal distinction or a distinction in class type is not clear.

In claim 1, line 6, the recitation of the pronoun "which" is indefinite. The object(s) referenced by "which" is/are not clear. Whether the pronoun "which" references "different label" and/or "particulate support" and/or "first signal-generating moieties" and/or "one or more first signal-generating moieties" and/or "second signal generating moiety" is not clear.

In claim 1, line 6, the recitation of the phrase "all said different labels" lacks antecedent basis. Whether said phrase references "a multiplicity of different labels" is not clear. The objects required for membership to the class "all" are not clear.

In claim 1, lines 6-7, the recitation of the infinitive "to generate" is indefinite. Whether generation of a clamped value signal is a required claim limitation, or merely intended, is not clear.

In claim 1, line 7, the recitation of the term "clamped" is indefinite. The characteristic(s) consisting or comprising a "clamped" object is/are not clear.

In claim 1, line 7, the recitation of the term "value" is indefinite. The physical and/or mathematical parameter(s) encompassed by "value" is/are not clear.

In claim 1, line 7, the recitation of the term "each" is indefinite. Whether "each" references an ordinal distinction or a distinction in class membership is not clear.

In claim 1, line 9, the recitation of the phrase "the one or more wavelengths that compose the characterizing signal" lacks antecedent basis.

In claim 1, line 9, the recitation of the pronoun "which" is indefinite. The object(s) referenced by "which" is/are not clear. Whether the pronoun "which" references "wavelength" and/or "signal" and/or "second signal-generating moiety" and/or "characterizing signal" is not clear.

In claim 1, line 11, the recitation of permissive language "permit" is indefinite. Whether verbiage subsequent to "permit" contains required claim limitations is not clear.

In claim 1, line 11, the recitation of the pronoun "them" is indefinite. The object(s) referenced by "them" is/are not clear.

In claim 1, line 11, the recitation of the infinitive "to interact" is indefinite. Whether interaction is a required claim limitation, or merely intended, is not clear.

In claim 1, line 12, the recitation of "desired" is indefinite. The standard for ascertaining the standard or degree of "desire" is not clear.

In claim 2, lines 1-2, the recitation of "said characterizing signal generating moieties" lacks antecedent basis.

In claim 2, line 2, the recitation of "each" is indefinite. Whether "each" references an ordinal distinction or a distinction in class type is not clear.

Claim Rejections - 35 USC § 102

Claims 1-4 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Nie et al. (US 2003/0148544).

Nie et al. describes a composition comprising a multiplicity of different labels, wherein each different label comprises a particulate support which is coupled both (a) to one or more first signal-generating moieties which together generate a visible characterizing signal that characterizes said label (see Fig. 1), and (b) to a second signal generating moiety directly attached to said particulate support which emits the same wavelength at the same intensity from all said different labels (see Fig. 7, paragraph [0088], "fluorophore", "quenching moiety") so as to generate a clamped value signal (see paragraph [0088], "luminescence of the fluorophore is quenched") from each said label, wherein the wavelength of the signal generated by said second signal-generating moiety (see paragraph [0088], "luminescence") is different from the one or more wavelengths that compose the characterizing signal which characterizes the label (see para. [0088], "emission code of the multicolor quantum dot-tagged bead"), and wherein said labels further contain reagents which permit each of them to interact specifically with a desired target (see paragraph [0088], "stem and loop structure").

With respect to claim 2, Nie et al. describe a composition comprising a multiplicity of different labels, wherein said characterizing signal generating moieties comprise at least two different signal generating entities wherein each of the entities generates a wavelength different from that generated by the other entity(s) and wherein the resulting signal of the labels resulting from said wavelength is varied among the different labels whereby each different label is thereby characterized by a different characterizing signal (see Fig. 1).

With respect to claim 3, Nie et al. describe a method to determine the distribution of multiple target substances in a sample which method comprises contacting said sample with the composition of claim 1, wherein the number of labels at a location in the sample is assessed by measuring the intensity of the clamped value signal emitted from the second signal generating moiety (see Fig. 5, para. [0069], "The intensity of the signal generated by the tag attached to the target molecule will be in direct proportion to the amount of target present in the sample").

With respect to claim 4, Nie et al. describe a method wherein the sample is displayed on a support suitable for viewing by microscopy (see Fig. 4a).

With respect to claim 7, Nie et al. describe a method wherein said particulate supports have diameters of 20-200 nm (see para. [0039]).

Claim Rejections - 35 USC § 103

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nie et al. (US 2003/0148544) is view of Kauvar et al. (US 2001/0044116).

Nie et al. describe a method for providing a pattern of target substances as substantially described supra. Nie et al. do not describe a method wherein the sample comprises intracellular environment or neural circuitry.

However, Kauvar et al. disclose a method using microscopy (See Fig. 1) to view intracellular targets (see p. 6, para. (0062], "cell or dendrites"') or neural circuitry (See p. 6, para. (0062], "dendrites"). Therefore, it would have been obvious for a person of ordinary skill in the art to combine the method of contacting an environment to view a pattern of particulate labels of Nie et al. with the method of using microscopy to view intracellular targets or neural circuitry of Kauvar et al. to provide a method of viewing a pattern of particulate labels in an intracellular or neural circuitry environment. A skilled artisan would have had a reasonable expectation of success in using the labels of Nie et al. in a method for viewing an intracellular environment because Nie et al. teach that the use of multicolor optical coding using luminescent QDs offers important advantages and applications that are not possible with other types of dyes (see para. [0017]). Nie et al. also teach that by using their labels, particulate beads can be quantified based on the observed number of quantum dots, i.e. intensity multiplexing.

Response to Arguments

In prior Office Action, claims 1-4 and 7 were rejected under 35 U.S.C. 102(e) as being anticipated by Nie et al. (US 2003/0148544). In response, Applicants amend claim 1 to add the limitation of a second signal generating moiety "directly attached to said particulate support". Applicants argue that Applicants intend to claim a composition wherein the "second signal generating moiety'" is attached to "a particulate support". Applicants argue that Nie et al. (US 2003/0148544) do not provide for such a second signal generating moiety attached to a particulate support (see Applicants' Reply, p. 7, first paragraph).

Applicants' argument has been carefully considered but is not persuasive. Nie et al. describe a "second signal generating moiety" in immediate physical association/communication/relationship/connection (i.e. directly attached) with said particulate support (see e.g., Fig. 5). Thus, Nie et al. continue to anticipate Applicants' invention, as claimed.

Conclusion

No claims are allowed at this time.

The prior art made of record, but not relied upon here, is considered pertinent to applicant's disclosure:

> Williams (US 5,310,539) is cited for his description of a composition comprising one or more first signal-generating moieties (see Title, "melanin") and a second signal generating moiety (see Abstract, "paramagnetic or superparamagnetic metals") generating a clamped value signal (see Abstract, "magnetic resonance"), relevant to claim 1.
>
> Meade et al. (US 5,900,228) are cited for their description of a composition comprising one or more first signal-generating moieties (see Title, "optical dye") and a second signal generating moiety (see Title, "MRI agent") generating a clamped value signal (see Abstract, "magnetic resonance"), relevant to claim 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv

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09/20/05